REMARKS

According to the Notice of Non-Compliant Amendment dated October 30, 2009, the listing of claims in Applicant's submission dated July 8, 2009, included incorrect claim identifiers. Please disregard the submission dated July 8, 2009, and instead enter claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 as set forth in the claim listing provided herewith. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 92-93 are pending and under examination.

Regarding 35 U.S.C. § 112, First Paragraph (Written Description)

Applicants respectfully traverse the rejection of claims 61, 71, 72, 74, 81, 85 and 86 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed.

The Examiner concludes that the specification provides insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15 , 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Office Action mailed January 8, 2009, page 6. The Examiner is respectfully reminded that the guidelines issued by the Patent Office in 1999 have now been superseded for almost a year-and- a half already by the newly revised written description guidelines issued in March 2008.1

Example 6 of the guidelines currently in effect concerns claims that are directed to nucleic acid molecules that hybridize to a recited sequence. This example provides three exemplary claims, onle of which reads as follows:

Claim 3: An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, wherein the nucleic acid hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1.

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1 Nevertheless, even under the 1999 guidelines the claims do not lack written description. Example 9 of the 1999 guidelines involves claims directed towards an isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of a disclosed sequence, wherein the nucleic acid encodes a protein having the functional activity of the protein encoded by the disclosed nucleic acid sequence. The 1999 guidelines find that this claim satisfies the written description requirement.

Concerning claim 3, the training materials acknowledge that "nucleic acids that hybridize to the complement of SEQ ID NO: 1 must share many nucleotides in common with SEQ ID NO: 1," and therefore, that "[t]he disclosure of SEQ ID NO: 1 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 1."2

In view of the above, Applicants respectfully request removal of the rejection of claims 61, 71, 72, 74, 81, 85 and 86 under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, had possession of the claimed invention at the time the application was filed.

Regarding 35 U.S.C. § 102

Applicants respectfully traverse the rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 91 and 92 under 35 U.S.C. § 102(b) as allegedly being anticipated by Qi et al., Abstract from British Journal of Cancer 69(5): 903-910, 1994). The Examiner alleges that Qi et al. discloses the increased expression (82%) of cripto-1 (CR-1) primary infiltrating ductal (IDCs) and infiltrating lobular breast carcinomas (ILCs) examined immunocytochemistry. According to the Examiner, absent evidence to the contrary the CR-1 described in Qi et al. is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention. **Cripto-1 (CR-1)** is a glycosylphosphatidylinositol (GPI)-anchored membrane glycoprotein that has been shown to play an important role in embryogenesis and cellular transformation. See Watanabe et al., J. Biol. Chem., 282(43):31643-31655 (2007), attached hereto as Attachment A. The rejected claims recite methods encompassing the **complement receptor type 1 (CR1)** gene, which encodes a single pass transmembrane glycoprotein that, through its ability to bind key components of the complement cascade, can inhibit both the classical and alternative pathways. **Cripto-1 (CR-1) and complement receptor type 1 (CR1) are distinct proteins encoded by distinct genes.** Applicants respectfully request removal of the rejection of claims 61 , 71 , 72 , 74 , 77- , 81 , 85, 91 and 92 under 35 U.S.C. § 102(b) as allegedly being anticipated by Qi et al.,

2 Claim 3 was ultimately deemed to be lacking writeen description on grounds that are inapplicable to this application, i.e. because one of ordinary skill in the art allegedly would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 1 would also encode a polypeptide that binds to NDG receptor and stimulates tyrosine kinase activity. The presently rejected claims do not recite a functional attributes and, therefore, do not lack written description as expressly stated in the above-cited excerpt from the 2008 Guidelines..

Abstract from *British Journal of Cancer* 69(5): 903-910 (1994).

Applicants respectfully traverse the rejection of claims 91 and 92 under 35 U.S.C. § 102(b) as allegedly being anticipated by Saeki et al., *Cancer Research* 52:3467-3473 (1992). Saeki allegedly discloses increased expression of cripto in human colorectal tumors in contrast to no expression of cripto in normal colon specimens. As described in more detail above, Cripto-1 (CR-1) and complement receptor type 1 (CR1) are distinct proteins encoded by distinct genes. Applicants respectfully request removal of the rejection of claims 91 and 92 under 35 U.S.C. § 102(b) as allegedly being anticipated by Saeki et al., *Cancer Research* 52:3467-3473 (1992).

Applicants respectfully traverse the rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 86, 91 and 92 under 35 U.S.C. §102(e) as being anticipated by U. S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4 2003). The Examiner alleges that the cited patent publication discloses diagnosing lung, colon and breast cancer with the assessment of cripto tumor polynucleotides and polypeptides via RT-PCR. As described in more detail above, Cripto-1 (CR-1) and complement receptor type 1 (CR1) are distinct proteins encoded by distinct genes. Applicants respectfully request removal of the rejection of claims 61, 71, 72, 74, 77-79, 81, 85, 86, 91 and 92 under 35 U.S.C. § 102(e) as allegedly anticipated by U. S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4 2003).

Regarding 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Qi et al., Abstract from *British Journal of Cancer* 69(5): 903-910 (1994), and further in view of U. S. Patent Application Publication number 2004/0054142 A1 and U. S. Patent 6,852 506. As set forth herein, the primary reference is directed to Cripto-1 (CR-1). As described in more detail above, Cripto-1 (CR-1) and complement receptor type 1 (CR1) are distinct proteins encoded by distinct genes. Accordingly, Qi et al., whether viewed alone or in combination with U. S. Patent Application Publication number 2004/0054142 A1 and U. S. Patent 6,852 506, does not teach or suggest the claimed methods reciting complement receptor type 1 (CR1). Applicants respectfully respectfully request removal of the rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Qi et al., Abstract from *British Journal of Cancer* 69(5): 903-910 (1994), and further in view of U. S. Patent Application Publication number 2004/0054142 A1 and U. S. Patent 6,852 506.

Applicants respectfully traverse the rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U. S. Patent Application Publication number 2004/0054142 in view of U. S. Patent 6,852 506. As set forth herein, the primary reference is directed to Cripto-1 (CR-1). As described in more detail above, Cripto-1 (CR-1) and complement receptor type 1 (CR1) are distinct proteins encoded by distinct genes. Accordingly, U. S. Patent Application Publication number 2004/0054142 A1, whether viewed alone or in combination with U. S. Patent 6,852 506, does not teach or suggest the claimed methods reciting complement receptor type 1 (CR1). Applicants respectfully respectfully request removal of the rejection of claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U. S. Patent Application Publication number 2004/0054142 A1, and U. S. Patent 6,852 506.

Regarding Nonstatutory Obviousness-Type Double Patenting

Claims 61, 71, 72, 74, 77-79, 81 and 85-89 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of co-pending USSN 10/573,332 (filed April 6 , 2007). Because this rejection is provisional and neither set of the allegedly conflicting claims has been allowed or patented, Applicants respectfully request deferral of this ground of rejection until there is an indication of allowable subject matter in one or both applications.

CONCLUSION

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned attorney if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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